

# Impax and DURECT Sign a \$63 Million Agreement to Develop and Commercialize DURECT's ELADUR® Pain Patch

HAYWARD, CA and CUPERTINO, CA, January 7, 2014 —Impax Laboratories, Inc.(NASDAQ: IPXL) and DURECT Corporation (Nasdaq: DRRX) announced today that they have entered into an agreement granting Impax the exclusive worldwide rights to develop and commercialize ELADUR®, DURECT's investigational transdermal bupivacaine patch for the treatment of pain associated with post-herpetic neuralgia (PHN).

Under the terms of the agreement, Impax will pay DURECT an upfront fee of \$2 million, with possible additional payments of up to \$61 million upon the achievement of predefined development and commercialization milestones. If ELADUR is commercialized, DURECT would also receive a tiered royalty on product sales. Impax will control and fund the development program.

"We're pleased to be moving ELADUR back into development through this collaboration with Impax," stated James E. Brown, president and CEO of DURECT. "Existing patches used to treat PHN pain are limited by their 12 hour duration, followed by a rest period in which the patient is not to wear a patch for 12 hours. Episodes of break-through pain are frequently reported to occur during rest periods for existing patches. We share a vision with Impax to develop a patch that has the potential to reduce these episodes of break-through pain."

Michael Nestor, president of Impax Pharmaceuticals added, "This agreement is another example of our commitment to building a strong brand pipeline through internal R&D and external business development. We are excited to collaborate with DURECT as this product could, if approved, fit well with the capabilities of our neurology focused specialty sales force."

ELADUR is an investigational transdermal drug patch intended to deliver bupivacaine for up to three days from a single application. DURECT has previously announced positive results for ELADUR from a 60 patient Phase IIa clinical trial of patients suffering from PHN.

### About Impax Laboratories, Inc.

Impax Laboratories, Inc. (Impax) is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of central nervous system disorder branded products. Impax markets its generic products through its Global Pharmaceuticals division and markets its branded products through the Impax Pharmaceuticals division. Additionally, where strategically appropriate, Impax develops marketing partnerships to fully leverage its technology platform and pursues partnership opportunities that offer alternative dosage form technologies, such as injectables, nasal sprays, inhalers, patches, creams and ointments. For more information, please visit the Company's Web site at:

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## **About DURECT Corporation**

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY®, POSIDUR™, ELADUR®, and TRANSDUR®-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit www.www.durect.com.

Impax Laboratories Forward-Looking Statement



To the extent any statements made in this news release contain information that is not historical, these statements are forwardlooking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the effect of current economic conditions on the Company's industry, business, financial position and results of operations, fluctuations in revenues and operating income, the Company's ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA, the Company's ability to successfully develop and commercialize pharmaceutical products in a timely manner, reductions or loss of business with any significant customer, the impact of consolidation of the Company's customer base, the impact of competition, the Company's ability to sustain profitability and positive cash flows, any delays or unanticipated expenses in connection with the operation of the Company's Taiwan facility, the effect of foreign economic, political, legal and other risks on the Company's operations abroad, the uncertainty of patent litigation, the increased government scrutiny on the Company's agreements with brand pharmaceutical companies, consumer acceptance and demand for new pharmaceutical products, the impact of market perceptions of the Company and the safety and quality of the Company's products, the difficulty of predicting FDA filings and approvals, the Company's ability to achieve returns on its investments in research and development activities, the Company's inexperience in conducting clinical trials and submitting new drug applications, the Company's ability to successfully conduct clinical trials, the Company's reliance on third parties to conduct clinical trials and testing, impact of illegal distribution and sale by third parties of counterfeits or stolen products, the availability of raw materials and impact of interruptions in the Company's supply chain, the use of controlled substances in the Company's products, disruptions or failures in the Company's information technology systems and network infrastructure, the Company's reliance on alliance and collaboration agreements, the Company's dependence on certain employees, the Company's ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, the Company's ability to protect its intellectual property, exposure to product liability claims, changes in tax regulations, the Company's ability to manage growth, including through potential acquisitions, the restrictions imposed by the Company's credit facility, uncertainties involved in the preparation of the Company's financial statements, the Company's ability to maintain an effective system of internal control over financial reporting, the effect of terrorist attacks on the Company's business, the location of the Company's manufacturing and research and development facilities near earthquake fault lines and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

## **DURECT Forward-Looking Statement**

The statements in this press release regarding ELADUR, its anticipated attributes, potential uses and commercial potential, and the milestone and royalty payments that may be potentially paid to DURECT under DURECT's license agreement with Impax are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, the risk that ELADUR may not receive regulatory approval, Impax's ability to design, enroll, conduct and complete clinical trials to support regulatory approval, and DURECT and Impax's ability to complete the design, development, and manufacturing process development of ELADUR, Impax's ability to manufacture and commercialize ELADUR, marketplace acceptance of the product candidate and the risk that Impax may terminate the agreement under conditions specified in the agreement. Further information regarding these and other risks is included in DURECT's Form 10-Q dated November 5, 2013 filed with the Securities and Exchange Commission under the heading "Risk Factors."

NOTE: ORADUR®, POSIDUR™, SABER®, TRANSDUR®, and ELADUR® are trademarks of DURECT Corporation. REMOXY, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

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